Safely prescribing potentially teratogenic medications to women

Imagine that your 35-year-old female patient has failed dietary management of her hyperlipidemia and needs a statin. Or, your 28-year-old female patient develops a new deep vein thrombosis while on oral contraceptives and needs warfarin. No problem, you say; or is there? Both women need medications that carry an FDA warning against use in pregnancy.

Reproductive-age women with medical problems like those listed above, as well as epilepsy, depression, hypertension, or other cardiac conditions, legitimately need medications that may be teratogenic: agents associated with birth defects. Case reports, registries, and recommendations abound. The FDA has a set of pregnancy risk categories based on testing or no testing of drugs in pregnant human subjects.

The science is evolving, but your patient needs treatment now. What should you do? In this first article within the series, our medical directors and FutureScripts® pharmacists, in collaboration with our Obstetrics Committee, will provide you with information and resources to assist you in determining the safest and most effective medication for your patient.

Why are teratogenic medications a concern? Consider the following:

- Fifty percent of pregnancies in the United States are unplanned and unintended.
- Organogenesis, the stage at which teratogens do their damage, is often complete before the woman realizes she is pregnant.
- Many commonly prescribed drugs have teratogenic potential.
- Other drugs can cause problems for neonates or nursing infants.

A study published recently in the *Annals of Internal Medicine* indicated that many physicians do not discuss potential teratogenicity with patients, even when prescribing a known teratogen (FDA Category X [contraindicated in pregnancy] or D [more risk than benefit in pregnancy] drugs).

Before you prescribe a potentially teratogenic medication, take a menstrual and contraceptive history and note the following:

- If there is *any* possibility your patient may be pregnant, or if you must prescribe something specifically contraindicated in pregnancy (Category X), perform a pregnancy test.
- If the patient is using contraception or has had a sterilization, or the drug you're going to use is *not* specifically contraindicated in pregnancy (current FDA Category X), prescribe the least teratogenic option you think is appropriate.

Discuss the following concerns with your patient:

- why you recommend this medication, its potential for reproductive harm, and other treatment options;
- why the patient needs effective birth control while on this potentially teratogenic medication. If you don't feel able to advise your patient about the specifics of contraception, refer your patient to someone who can.
- why, especially now, she needs to plan pregnancy so that
  - she is stabilized on the least teratogenic but most effective regimen prior to pregnancy;
  - the risks can be addressed if there is no alternative to current medication.

If your patient does become pregnant:

- Advise her not to stop taking the medication without speaking with you and that she should immediately contact your office.
- Remember that potential harm to the fetus must be weighed against potential harm from stopping the medication, which might injure both mother and fetus.
- Consult with an OB/GYN, perinatologist (MFM), or pharmacist before prescribing a medication that may have a teratogenic effect.

Be sure to document all your discussions with the patient.

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Partners in Health Update will keep you advised of when the next article on specific issues of teratogenic medications by drug type will be available on our website.

IBC makes no guarantees regarding the accuracy of the information contained therein.

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Note: This article contains information from the following sources:

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LactMed (NLM) website. Available at *http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT.* LactMed is a database of drugs and other chemicals to which breastfeeding mothers may be exposed.

March of Dimes Birth Defects Foundation (MOD) website. Available at *www.marchofdimes.com.* The MOD site links to the MOD Pregnancy & Newborn Health Education Center for information on birth defects. The Center can also be contacted by email or through its Info Now chat function.

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Motherisk website. Available at *www.motherisk.org.* Motherisk provides evidence based information about the safety or risk of drugs, chemicals, and disease during pregnancy and lactation.

Organization of teratology information specialists (OTIS). Available at *www.otispregnancy.org.* Viewed October 23, 2007.

Reprotox. Developed by the Reproductive Toxicology Center for its members, REPROTOX contains summaries on the effects of medications, chemicals, infections, and physical agents on pregnancy, reproduction, and development. *www.reprotox.org.* Viewed February 14, 2008.

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Cohen LS, Altshuler LL, Harlow BL, et al. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. JAMA. 2006; 295;499-507.

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